February 6, 2025

Guangzhou CHUANG ZAO MEI Technology Co., Ltd.
% Asher William
Regulatory Affairs Manager
AskWay Innovative Ltd.
4F, Yuehuayuan Building, 2008 Nanshan Avenue
Nanshan Street Nashan District
Shenzhen, 518000
China

Re: K243465
Trade/Device Name: Diode Laser Hair Removal Device (EVOLUTION MEDICAL); Diode Laser Hair Removal Device (M-I-X MEDICAL); Diode Laser Hair Removal Device (GENESIS); Diode Laser Hair Removal Device (Lotus); Diode Laser Hair Removal Device (Ultimate)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 8, 2024
Received: November 8, 2024

Dear Asher William:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.02.06 22:01:16 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243465

Device Name
Diode Laser Hair Removal Device (EVOLUTION MEDICAL); Diode Laser Hair Removal Device (M-I-X MEDICAL); Diode Laser Hair Removal Device (GENESIS); Diode Laser Hair Removal Device (Lotus); Diode Laser Hair Removal Device (Ultimate)

Indications for Use *(Describe)*
The Diode Laser Hair Removal Device (Model: EVOLUTION MEDICAL, M-I-X MEDICAL, GENESIS, Lotus and Ultimate) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) #:

510(k) Summary

Prepared on: 2025-02-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Guangzhou CHUANG ZAO MEI Technology Co.,Ltd.
Applicant Address	Dehe international A505,No.2,Qixinggang Industrial Road, JUNHE street,Baiyun District Guangzhou Guangdong 510440 China
Applicant Contact Telephone	13242057537
Applicant Contact	Mr. SERGEI SLASHCHILIN
Applicant Contact Email	info@icbtech.pro
Correspondent Name	AskWay Innovative Ltd.
Correspondent Address	4F, Yuehuayuan Building, 2008 Nanshan Avenue, Nanshan Street Nashan District Shenzhen CN 518000 China
Correspondent Contact Telephone	13342086538
Correspondent Contact	Mr. Asher William
Correspondent Contact Email	Asher@cx.cx

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Diode Laser Hair Removal Device (EVOLUTION MEDICAL); Diode Laser Hair Removal Device (M-I-X MEDICAL); Diode Laser Hair Removal Device (GENESIS); Diode Laser Hair Removal Device (Lotus); Diode Laser Hair Removal Device (Ultimate)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code(s)	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221312	Diode Laser Hair Removal Device	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The Diode Laser Hair Removal Device is a surgical device intended for use in dermatologic and general surgical procedure. It utilizes a diode laser as a laser source (808 nm). The laser power is delivered to the treatment area via a laser handpiece. The emission laser is activated by a foot switch and a laser handpiece.
There are five models included, EVOLUTION MEDICAL, M-I-X MEDICAL, GENESIS, Lotus, and Ultimate, the five models have same

mechanism of action, principle and specification, with only one difference: the adjustable range of Energy density is different, EVOLUTION MEDICAL (1-77 J/cm^2), M-I-X MEDICAL (1-70 J/cm^2), GENESIS(1-74 J/cm^2), Lotus(1-67 J/cm^2), and Ultimate(1-65 J/cm^2).
Changes to the device include the addition of a remote link to the device to obtain and back up the device's usage data, a remote upgrade function, and the ability to provide a URL for users to download the device's usage data, as compared to previously listed devices.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Diode Laser Hair Removal Device (Model: EVOLUTION MEDICAL, M-I-X MEDICAL, GENESIS, Lotus and Ultimate) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Diode Laser Hair Removal Device (EVOLUTION MEDICAL, M-I-X MEDICAL, GENESIS, Lotus, and Ultimate) has same indications for use with the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The Diode Laser Hair Removal Device (EVOLUTION MEDICAL, M-I-X MEDICAL, GENESIS, Lotus, and Ultimate) models have the same laser treatment output wavelength of 808 nm, pulsewidth range of 3-320 milliseconds, and repetition rate range of 1 – 10 Hz, as the predicate device models (EVOLUTION MEDICAL, M-I-X MEDICAL). The treatment window size of 12 millimeters (mm) X 18 mm for the proposed models in this 510(k) is smaller than the predicate device's 12.6 mm X 20.06 mm. The proposed models have the following fluence ranges: EVOLUTION MEDICAL: 1-77 J/cm2, M-I-X MEDICAL: 1-70 J/cm2, GENESIS: 1-74 J/cm2, Lotus: 1-67 J/cm2, Ultimate: 1-65 J/cm2, while the predicate models have the following fluence ranges: EVOLUTION MEDICAL: 1-77 J/cm2, M-I-X MEDICAL: 1-70 J/cm2. The proposed device also includes wireless connectivity to a computer server to store device settings and to allow for software upgrades. The proposed device models' fluence ranges, the change in treatment window size, and the proposed device's additional wireless connectivity, are considered to be acceptable with regard to the proposed device's safety and efficacy for the proposed indications for use.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] (Consolidated Text), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)].

IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

IEC 60601-2-22 Edition 3.1 2012-10, Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment.

IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification and requirements.

ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility).

ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization. (Biocompatibility).

IEEE ANSI USEMCSC C63.27-2021, American National Standard for Evaluation of Wireless Coexistence.

AAMI TIR69:2017/(R2020), Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.

Cybersecurity Testing was conducted per the latest FDA Guidance titled "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" issued on September 27, 2023.

Performance Testing for Energy Output Accuracy.

Software Verification and Validation Testing was conducted per the latest FDA Guidance titled "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, and the level of concern was determined to be Moderate for the proposed device.

Conclusion:
Based on the comparison and analysis above, the proposed device is determined to be as safe, as effective, and performs as well as the predicate device.